

II. Rejections under § 102(e) over Nickolson

The Examiner has rejected claims 44 and 45 under 35 U.S.C. § 102(e) as being anticipated by Nickolson. The Examiner cites claim 1, which recites a combination of mirtazapine with other compounds. Again, the Examiner has not identified any portion of Nicholson describing an adduct of mirtazapine and water. Therefore, Applicants respectfully request that this rejection be withdrawn.

III. Rejections under § 102(b) over Kaspersen

The Examiner has rejected claims 29-43 under 35 U.S.C. § 102(b) as being unpatentable over Kaspersen et al. The Examiner acknowledges that Kaspersen does not disclose adducts of mirtazapine and water. Rather, the Examiner asserts that the products disclosed in Kaspersen are “presumed” to be the claimed adduct (i.e., inherently formed) because Kaspersen’s crystallization process “appears to be the same” as Applicants’. Applicants respectfully disagree.

“To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result form a given set of circumstances is not sufficient.” MPEP §2112.

Kaspersen discloses “crystallization from methanol/water (1:1, v/v) yielding 600 mg (53%) Org 3770 as colorless crystals . . .” Kaspersen, however, does not disclose the formation of an adduct of mirtazapine and water. Merely crystallizing with methanol/water does not necessarily lead to the formation of the claims adducts. Indeed, neither the specification nor the claims suggest that any crystallization from methanol/water (1:1, v/v) would result in the formation of the claimed adducts. To the contrary, in one embodiment, for example, Applicants add water slowly to the mirtazapine solution. Thus, because Kaspersen does not disclose a method known to form an adduct of mirtazapine and water and does not disclose a method described in the specification to form such an adduct, the product disclosed in Kaspersen is not inherently an adduct of mirtazapine and water. Accordingly, Applicants’ respectfully request that this rejection be withdrawn.

IV. Rejections under § 112, Second Paragraph

The Examiner has rejected claims 36 and 42 under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Examiner states that claims 36 and 42 appear to be duplicates of claim 30. Applicants respectfully disagree.

Applicants have the right to restate the invention in a reasonable number of ways. A mere difference in scope between claims has been held by the courts to be permissible. MPEP § 706.03(k). Claim 30 is a composition claim directed to an adduct of mirtazapine and water. In contrast, claims 36 and 42 are product-by-process claims, each limited to an adduct of mirtazapine and water prepared according to their respective processes. Because claims 36 and 42 recite process limitations not present in claim 30, these three claims are of different scope and are not duplicative. Accordingly, Applicants respectfully request that this rejection be withdrawn.

V. Conclusion

In view of the foregoing remarks, Applicants respectfully request allowance of the pending claims. The Commissioner is hereby authorized to charge any fees which may be necessary for consideration of this paper to Kenyon & Kenyon Deposit Account No. 11-0600. A copy of this sheet is enclosed for that purpose.

Respectfully submitted,

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